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EXAMINER	
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ART UNIT	**PAPER NUMBER**
4133	
MAIL DATE	**DELIVERY MODE**
04/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,258	ISHIKAWA, MANABU	
	Examiner	Art Unit	
	SHADI ALIKHANI	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-22 and 29-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

3. Regarding claim 2, It is unclear what the applicant means by "and has an outer diameter is enlarged with the tip end of the dilator" on page 2, ln 20. It is also unclear what the applicant means by “toward an apart side from a side in the vicinity of the tip” on page 2, ln 25-26.

4. Regarding claim 4, the applicant seems to be claiming "an enlarged diameter portion" and a "large diameter portion having a diameter enlarged.” This has caused the claim to be unclear. Which is the portion with an enlarged diameter?

5. Regarding claim 29 and 30, on lines 13-14, the applicant has discloses “dilator insertion portion bulges in a direction deviating from the axis of the dilator.” It is unclear and confusing whether this is the same "bulging portion" that is claimed in claim 30 on line 25 by the applicant as “the trocar hold portion includes a bulging portion,” since they are both located on the trocar hold portion.

6. Regarding claim 30, it is unclear what the applicant means by "apart from the tip end of the dilator insertion portion from a side in the vicinity of the tip end of the dilator insertion

portion and at least a part of which is covered with the dilator hold portion in a state in which the sheath insertion portion is inserted in the dilator insertion portion."

7. Regarding claim 31, the applicant seems to be claiming "an enlarged diameter portion" and a "large diameter portion having a diameter enlarged." This has caused the claim to be unclear. Which is the portion with an enlarged diameter?

Claim rejections below were made as best understood by the examiner in light of the rejections under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 9, 14, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Farrell (US 4,994,027).

Regarding claim 1, Farrell discloses a system that includes a series of dilator sleeves or a "trocar system." Farrell discloses an elongated probe (16) including a first central axis and a tip end for forming a punctured hole in a living tissue (Fig. 1A & 3).

Additionally, Farrell discloses a cylindrical sheath (18) including tip and base ends, second central axis and a through hole extending along the second central axis between the tip

and base ends (Fig. 1C), the sheath being adapted so that the tip end of the probe projects from the tip end of the sheath (Fig. 2A), when the probe is inserted in the through hole of the sheath (Fig. 3 & 4) so as to align the first central axis with the second central axis.

Farrell also discloses a cylindrical dilator (19) including tip and base ends, a third central axis, a through hole extending along the third central axis between the tip and base ends, and a punctured hole dilating portion (14") to dilate the punctured hole formed in the living tissue by the tip end of the probe in the tip end of the dilator (Fig. 3), the dilator being adapted so that the tip end of the sheath projects from the tip end of the dilator (Fig. 2A), when the sheath is inserted in the through hole of the dilator so as to align the second central axis with the third central axis.

FIG. 1A

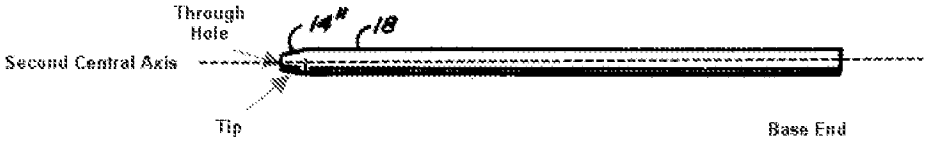

FIG. 1C

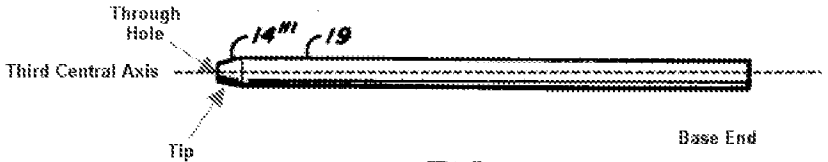

FIG. 1D

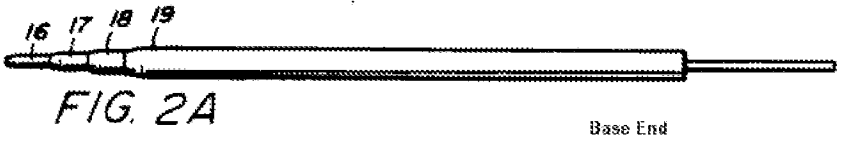

FIG. 2A

Farrell additionally discloses a cylindrical trocar (24) including tip and base ends, a fourth central axis and a through hole extending along the fourth central axis between the tip and base ends, the trocar being adapted so that the tip end of the dilator projects from the tip end of the trocar (Fig. 3 & 4), when the dilator is inserted in the through hole of the trocar so as to align the third central axis with the fourth central axis, the probe, sheath and dilator being removed from the through hole of the trocar to retain the trocar in a patient's body wall (col. 3, ln 2-9; col. 3, ln 60-68; col. 4, ln 1-8) after guiding the trocar between the tip and base ends into the punctured hole.

Farrell also discloses an engaging mechanism (Fig. 2C & 3; col. 1, ln 48-52; col. 3, ln 2-10; col. 3, ln 60-68) to detachably engage the dilator with the trocar in a state in which the dilator is inserted in the trocar and a hold portion (Fig. 3 & 4) by which the base ends of the trocar and the dilator are connected and integrated with each other in a state in which the trocar is engaged with the dilator by the engaging mechanism (col. 2, ln 46-52; col. 1, ln 48-52).

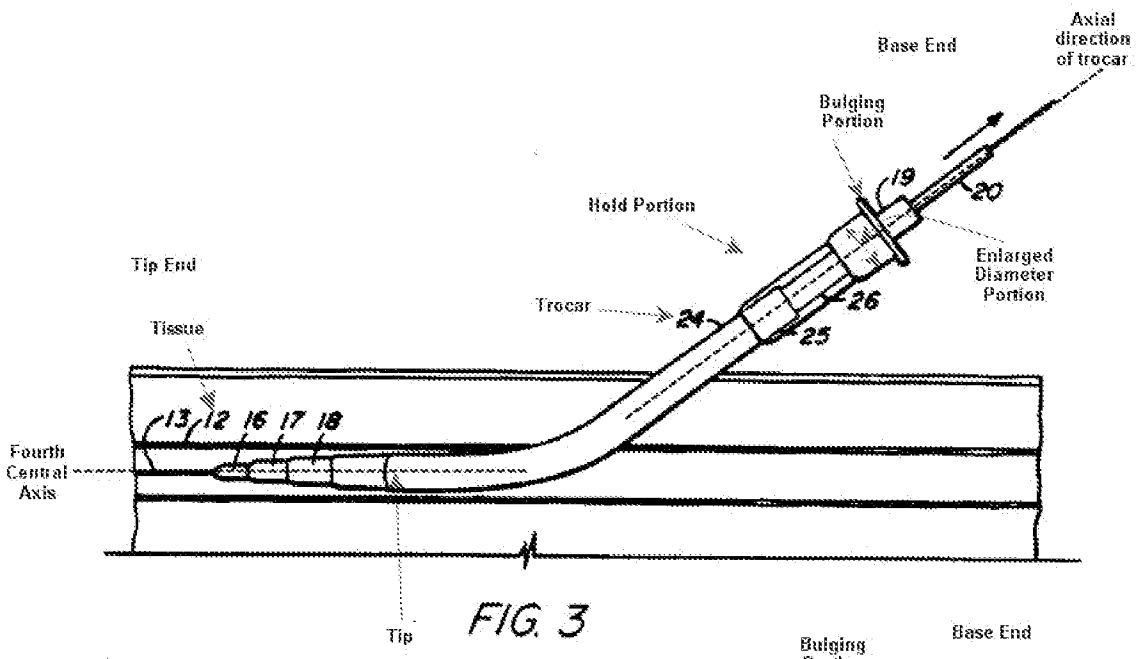

FIG. 3

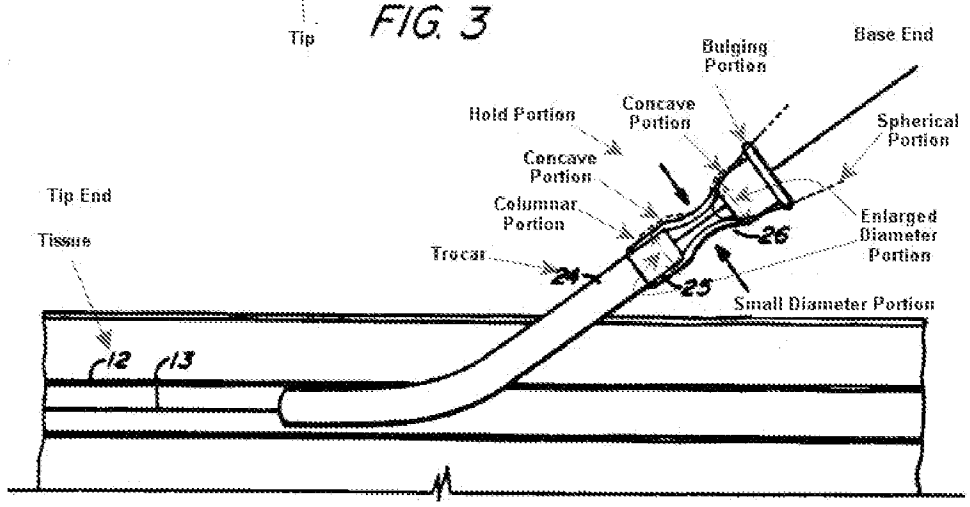

FIG. 4

10. Regarding claim 2, Farrell discloses a hold portion (Fig. 3) with an enlarged diameter portion, which is disposed on the base end of the dilator and has an outer diameter that is enlarged with the tip end of the dilator (Fig. 3 & 4).

Farrell also discloses a bulging portion disposed on the base end of the trocar and formed of at least a part of the base end of the trocar projected in a direction deviating from the axial direction of the trocar toward a side in the vicinity of the tip end of the trocar (Fig. 3 & 4).

11. Regarding claim 3, Farrell discloses enlarged diameter portion that includes a concave portion (Fig. 4) in which at least a portion of the base end of the trocar on a side apart from the tip end of the trocar is to be fitted on a side in the vicinity of the tip end of the dilator.

12. Regarding claim 4, Farrell discloses an enlarged diameter portion that includes a small diameter portion (Fig. 4) to be held by the operator's finger, and a large diameter portion having a diameter enlarged toward the tip end of the dilator as compared with the small diameter portion and the concave portion formed therein (Fig. 4).

13. Regarding claim 9, Farrell discloses that the enlarged portion includes a spherical portion to be held by an operator's hand and the spherical portion includes the concave portion inside (Fig. 4).

14. Regarding claim 14, Farrell discloses that the enlarged portion includes a columnar portion to be held by an operator's hand and the columnar portion includes the concave portion inside (Fig. 4).

15. Regarding claim 27, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

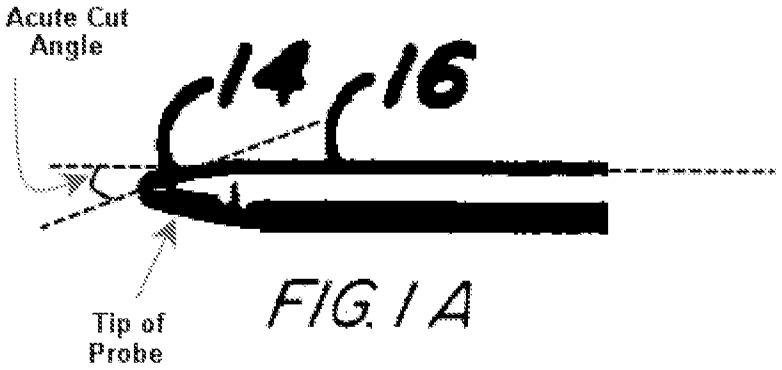

FIG. 1A

16. Regarding claim 29, Farrell discloses a system that includes a series of dilator sleeves or a "trocar system." Farrell discloses an elongated probe (16) including a first central axis and a tip end for forming a punctured hole in a living tissue (Fig. 1A & 3).

Additionally, Farrell discloses a cylindrical sheath (18) including tip and base ends, second central axis and a through hole extending along the second central axis between the tip and base ends (Fig. 1C), the sheath being adapted so that the tip end of the probe projects from the tip end of the sheath (Fig. 2A), when the probe is inserted in the through hole of the sheath (Fig. 3 & 4) so as to align the first central axis with the second central axis.

Farrell also discloses a cylindrical sheath insertion portion (19) including tip and base ends, a third central axis, a through hole extending along the third central axis between the tip and base ends, and a punctured hole dilating portion (14") to dilate the punctured hole formed in the living tissue by the tip end of the probe in the tip end of the sheath insertion portion (Fig. 3), the sheath insertion portion being adapted so that the tip end of the sheath projects from the tip end of the sheath insertion portion (Fig. 2A), when the sheath is inserted in the through hole of the sheath insertion portion so as to align the second central axis with the third central axis (Fig. 3 & 4).

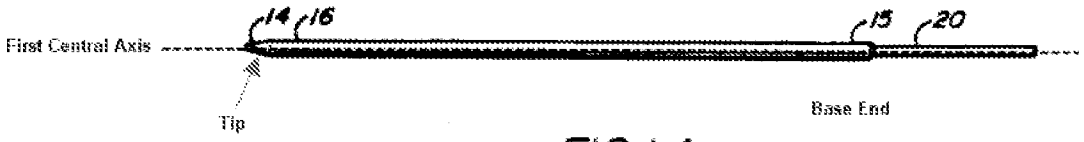

FIG. 1A

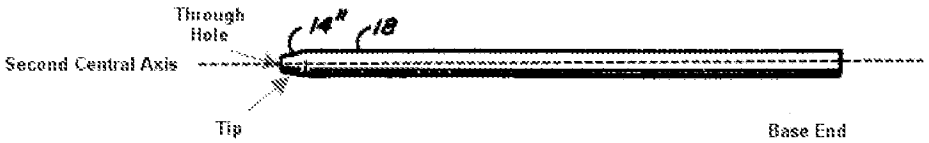

FIG. 1C

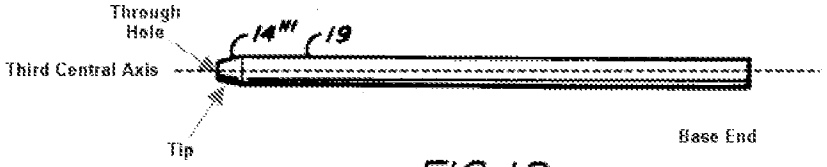

FIG. 1D

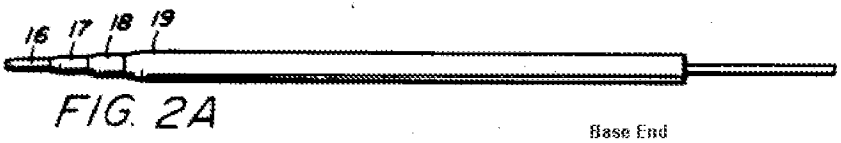

FIG. 2A

Farrell additionally discloses a trocar or a "cylindrical dilator insertion portion" (24) including tip and base ends, a fourth central axis and a through hole extending along the fourth central axis between the tip and base ends, the dilator insertion portion being adapted so that the tip end of the sheath insertion portion projects from the tip end of the dilator insertion portion (Fig. 3 & 4), when the sheath insertion portion is inserted in the through hole of the dilator insertion portion so as to align the third central axis with the fourth central axis, the probe, sheath and sheath insertion portion being removed from the through hole of the dilator insertion portion to retain the dilator insertion portion in a patient's body wall (col. 3, ln 2-9; col. 3, ln 60-68; col.

4, ln 1-8) after guiding the dilator insertion portion between the tip and base ends into the punctured hole (Fig. 3 & 4).

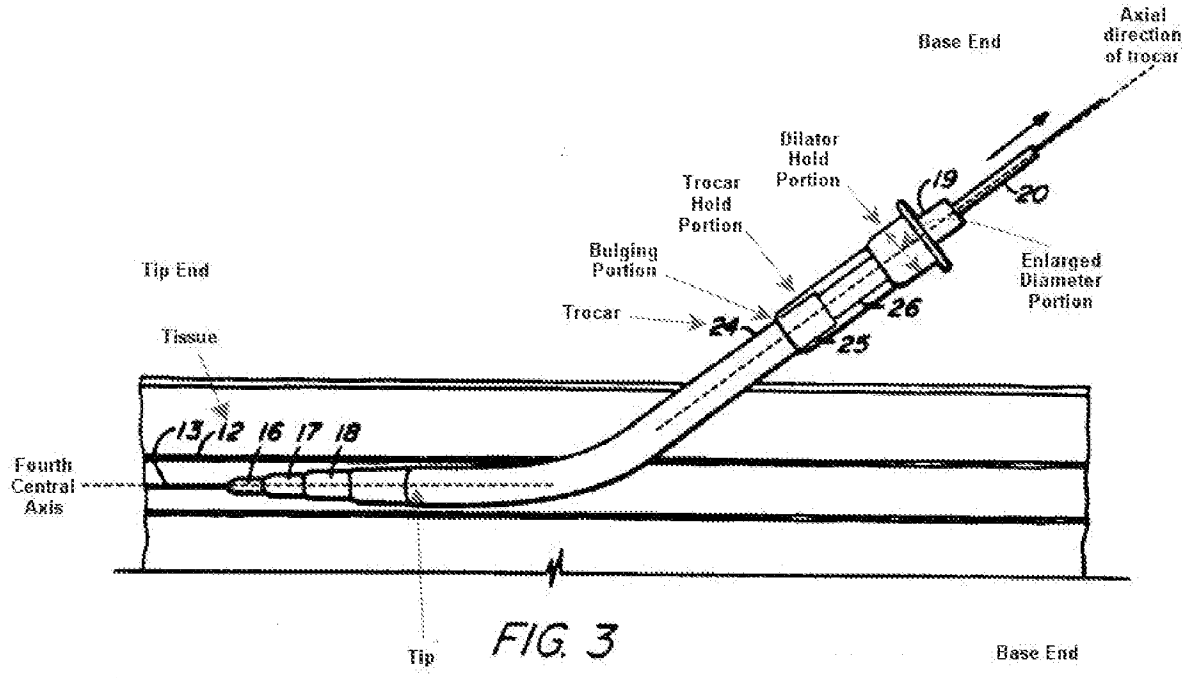

FIG. 3

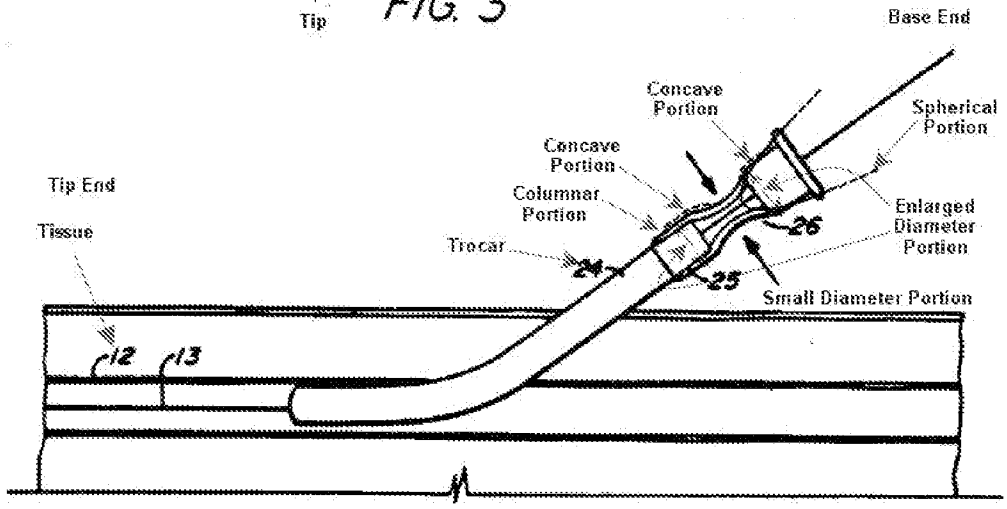

FIG. 4

Farrell discloses a dilator hold portion (Fig. 3) which is disposed on the base end of the sheath insertion portion so as to be held by the operator in a state in which the sheath insertion

portion is inserted in the dilator insertion portion and has an outer diameter enlarged with respect to the tip end of the sheath insertion portion (Fig. 3).

Farrell also discloses a trocar hold portion (Fig. 3), which is disposed on the base end of the dilator insertion portion so as to be held by the operator in a state in which the sheath insertion portion is inserted in the dilator insertion portion, which has a portion on a side in the vicinity of the tip end of the dilator insertion portion that bulges (Fig. 4) in a direction deviating from the axis of the dilator insertion portion, and a portion on at least a side apart from the tip end of the dilator insertion portion is held by the dilator hold portion in a state in which the sheath insertion portion is inserted in the dilator insertion portion.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 5-7, 10-12, 15-17, 19-21, 24-25, 30-34, 37-39, 41-44, 46-48, 51-52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrell (US 4,994,027) in view of Maaskamp et al (US 6,013,046) or Maaskamp herein.

Regarding claim 5, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the trocar and whose diameter is enlarged apart from the tip end of the trocar (col 2, ln 64-67).

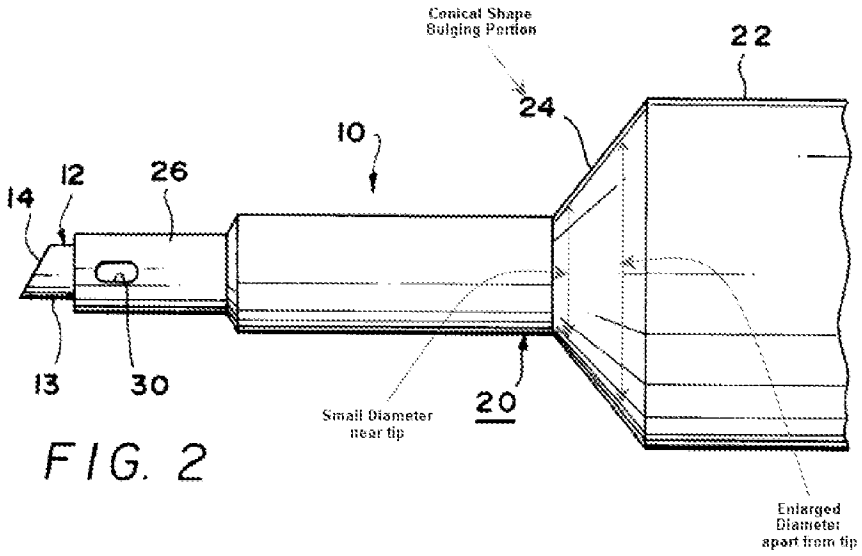

FIG. 2

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of

the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

20. Regarding claim 6, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

21. Regarding claim 7, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

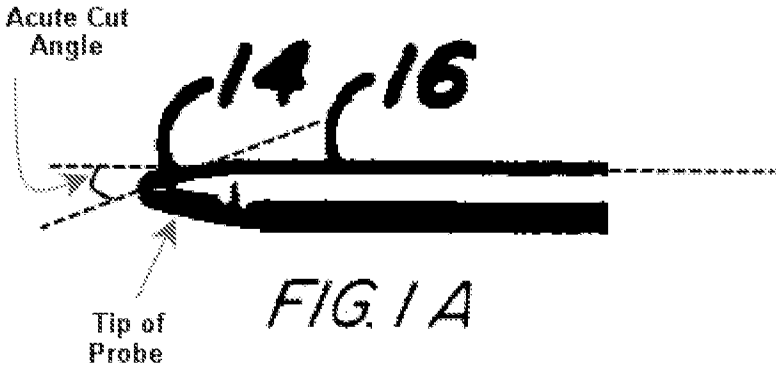

FIG. 1A

22. Regarding claim 10, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the trocar and whose diameter is enlarged apart from the tip end of the trocar (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

23. Regarding claim 11, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an

encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

24. Regarding claim 12, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

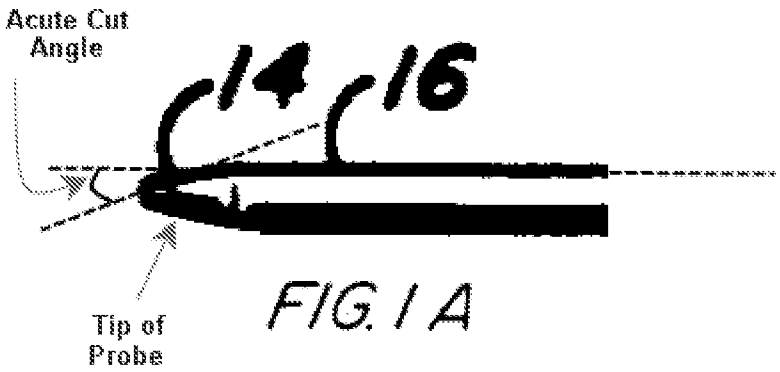

FIG. 1A

25. Regarding claim 15, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device (Fig. 2) that has a conical shape having a small diameter on the side in the vicinity of the tip end of the trocar and whose diameter is enlarged apart from the tip end of the trocar (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

26. Regarding claim 16, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

27. Regarding claim 17, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

28. Regarding claim 19, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the trocar and whose diameter is enlarged apart from the tip end of the trocar (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

29. Regarding claim 20, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be

capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

30. Regarding claim 21, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

31. Regarding claim 24, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end.

The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

32. Regarding claim 25, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

33. Regarding claim 30, Farrell discloses a dilator hold portion, which includes an enlarged diameter portion (Fig. 3) whose diameter is enlarged with respect to the tip end of the sheath insertion portion and a trocar hold portion (Fig. 3) that with a bulging portion. Farrell does not appear to explicitly disclose that the bulging portion is projected in a direction deviating from the axial direction of the dilator insertion portion (Fig. 3 & 4) toward a side of the trocar hold portion apart from the tip end of the dilator insertion portion from a side in the vicinity of the tip end of the dilator insertion portion and at least a part of which is covered with the dilator hold portion in a state in which the sheath insertion portion is inserted in the dilator insertion portion.

However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the dilator insertion portion and whose diameter is enlarged apart from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The

motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

34. Regarding claim 31, Farrell discloses that the enlarged diameter portion includes a small diameter portion to be held by the operator's finger and a large diameter portion whose diameter is enlarged toward the tip end of the sheath insertion portion as compared with the small diameter portion and the concave portion formed therein (Fig. 4).

35. Regarding claim 32, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the dilator insertion portion and whose diameter is enlarged apart from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the

device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

36. Regarding claim 33, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

37. Regarding claim 34, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

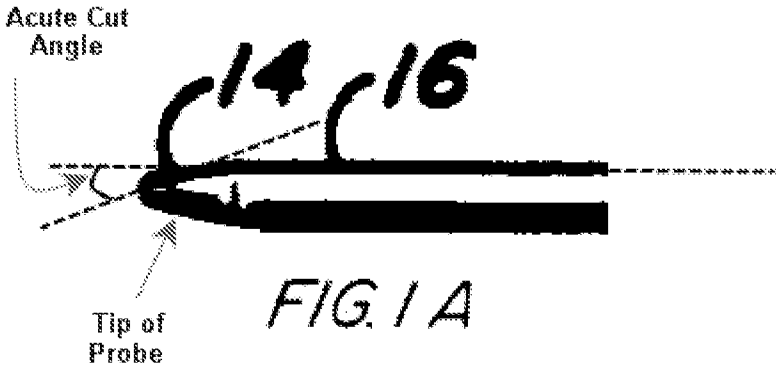

FIG. 1A

38. Regarding claim 36, Farrell discloses an enlarged diameter portion that includes a spherical portion to be held by an operator's hand and the spherical portion includes the concave portion inside (Fig. 3 & 4).

39. Regarding claim 37, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the dilator insertion portion and whose diameter is enlarged apart from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

40. Regarding claim 38, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

41. Regarding claim 39, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

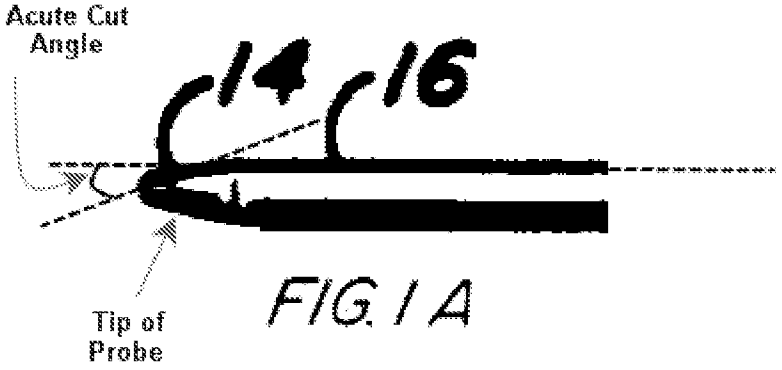

FIG. 1A

42. Regarding claim 41, Farrell discloses that the enlarged portion includes a columnar portion to be held by an operator's hand and the columnar portion includes the concave portion inside (Fig. 4).

43. Regarding claim 42, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the dilator insertion portion and whose diameter is enlarged apart from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

44. Regarding claim 43, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing

sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

45. Regarding claim 44, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

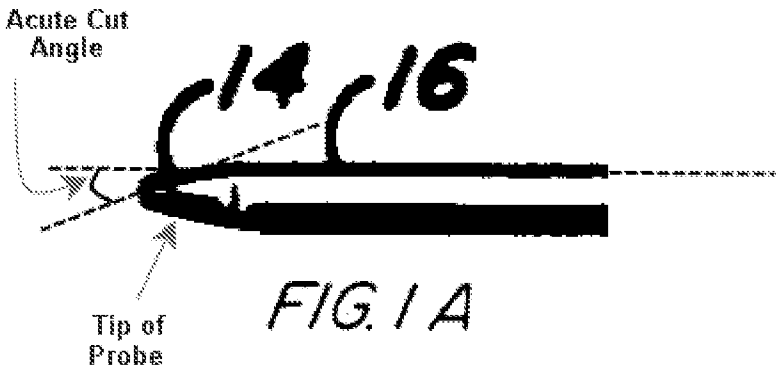

FIG. 1A

46. Regarding claim 46, Farrell discloses a bulging portion (Fig. 3 & 4). Farrell does not appear to explicitly disclose that the bulging portion has a conical shape. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the dilator insertion portion

and whose diameter is enlarged apart from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

47. Regarding claim 47, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

48. Regarding claim 48, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

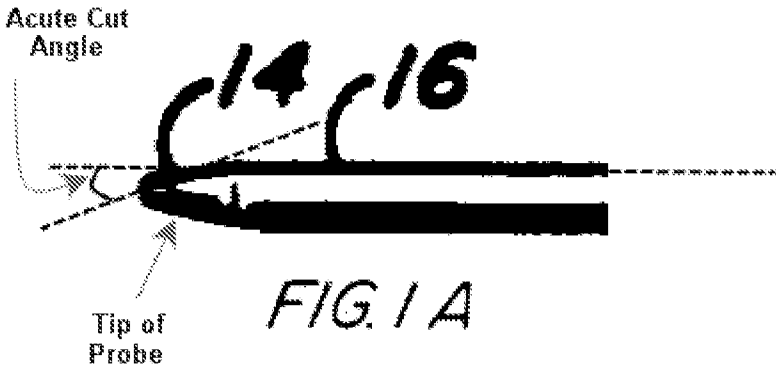

FIG. 1A

49. Regarding claim 51, Farrell discloses the probe (16). Farrell does not appear to explicitly disclose that the probe includes an ultrasonic transducer capable of transmitting an ultrasonic vibration toward the tip end of the probe. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

50. Regarding claim 52, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

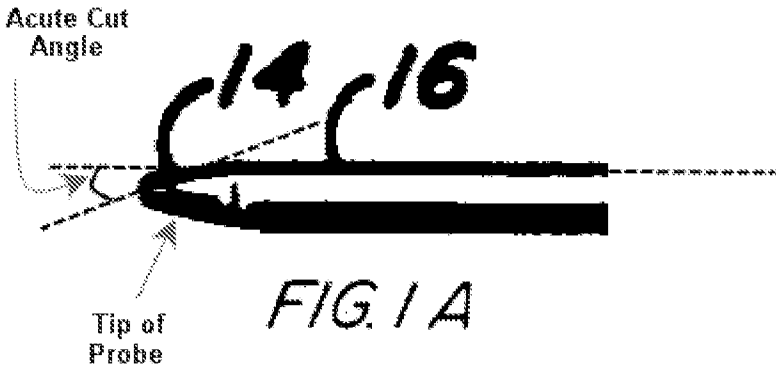

FIG. 1A

51. Regarding claim 54, Regarding claim 52, Farrell discloses a tip end of the probe, which has a conical shape (Fig. 1A) and has a surface cut at an acute cut angle with respect to the axial direction of the probe (col. 1, ln 37-42).

52. Claims 8, 13, 18, 22, 26, 28, 35, 40, 45, 49, 53, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrell (US 4,994,027) in view of Maaskamp et al (US 6,013,046) or Maaskamp herein, further in view of Kambin (US 4,573,448).

53. Regarding claim 8, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

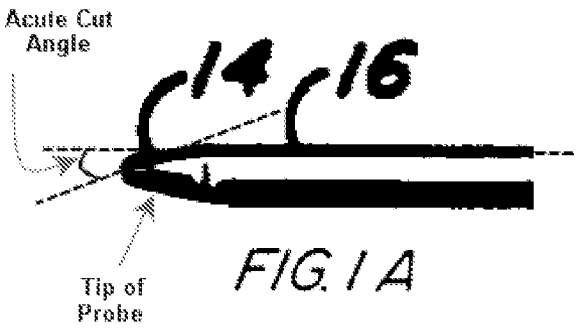

FIG. 1A

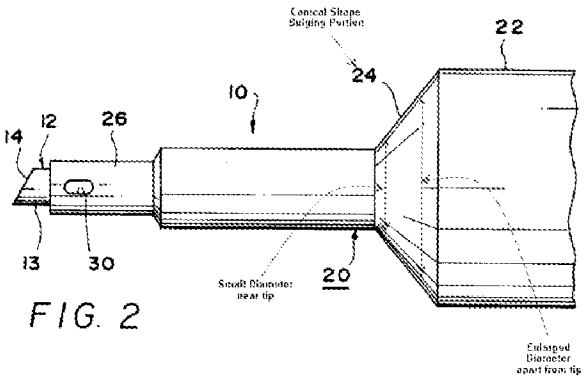

FIG. 2

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

54. Regarding claim 13, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to

advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

55. Regarding claim 18, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

56. Regarding claim 22, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify

the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

57. Regarding claim 26, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

58. Regarding claim 28, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

59. Regarding claim 35, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

60. Regarding claim 40, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over

a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

61. Regarding claim 45, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

62. Regarding claim 49, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

63. Regarding claim 53, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to

advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

64. Regarding claim 55, Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp appear to disclose that the cut angle is 60 degrees or less with respect to the axial direction of the probe and is over a vertical angle of the tip end of the probe. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

65. Claims 23 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrell (US 4,994,027) in view of Kambin (US 4,573,448).

Regarding claim 23, Farrell discloses a hold portion (Fig. 4). Farrell does not appear to explicitly disclose that the hold portion includes at least one slip stopper. However, Kambin discloses a grip portion (44) or a "hold portion" that includes at least one slip stopper (Fig. 8), which prevents the hold portion from slipping from the operator's hand (col. 3, ln 49-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Kambin before him or her to modify the multi-sleeve trocar device of Farrell to include a hold portion with at least one slip stopper. The motivation for doing so would have been to provide a more effective hold portion that can better control handling of the device when being used by the operator.

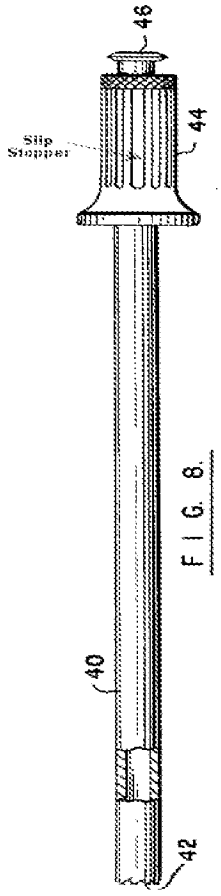

FIG. 8.

66. Regarding claim 50, Farrell discloses a hold portion (Fig. 4). Farrell does not appear to explicitly disclose that the hold portion includes at least one slip stopper. However, Kambin discloses a grip portion (44) or a "hold portion" that includes at least one slip stopper (Fig. 8), which prevents the hold portion from slipping from the operator's hand (col. 3, ln 49-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Kambin before him or her to modify the multi-sleeve trocar device of Farrell to include a hold portion with at least one slip stopper. The motivation for doing so would have been to provide a more effective hold portion that can better control handling of the device when being used by the operator.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Polk et al. (US 4,535,759) discloses an ultrasonic friction reducing device. Zaleski (US 5,993,408) discloses a thin tip phaco needle for enabling passage of debris from a surgical site. Stouder (US 5,746,720) discloses an adjustable length cannula and trocar in order to accommodate a range of body cavities. Adams et al. (US 5,385,562) discloses a guide catheter system for guiding an angioplasty balloon catheter into a patient's vascular system. Ichikawa (US 4,981,482) discloses a multilayer tube device for forming a fistula. Parris et al. (US 5,976,115) discloses a blunt cannula spike adapter assembly with diametrically opposed surface portions. Vaillancourt (US 4,655,750) discloses a catheter system for introduction and placement of a flexible catheter into the lumen of an artery or vein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHADI ALIKHANI whose telephone number is (571)270-5305. The examiner can normally be reached on Monday - Thursday 10AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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3/28/2008
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